HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL 5881-0
January 10, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles Butrey, M.D.
President
Tri-City Family Medicine, Inc. Diagnostic Center
Mammography Department
1204 East Broad St.
Elyria, OH 44035

Facility I.D.#: 183897

Dear Dr. Butrey:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on December 21, 2000. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following **repeat** Level 2 finding at your facility:

Quality Assurance-Equipment - 21 CFR 900.12 (e)(2)(i)-(iv)

> Your records revealed that your facility phantom quality control documents for the mammography unit were missing for at least two weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test. The inspection found that your facility failed to perform this quality control test during the weeks of November 22 –24, & 26 and November 29 & 30, December 1-3, 1999. Your records indicated during these two weeks, mammography were performed on patients.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received. The problem is identified as **repeat** Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the problem found during your previous inspection on October 12, 1999.

Because the condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site

monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 and 3 findings that are listed in the inspection report that was provided to you. These findings are:

Level 2 Findings:

1. Surveys – 21 CFR 900.12 (e)(9) and as required by 21 CFR 900.12 (e)(1)-(7)
The medical physicist's annual survey for the mammography unit is incomplete for reason the following evaluations were not performed:

a. Automatic exposure control (AEC) performance capability:
- Tests not perform for 2, 4, & 6 cm. phantoms thickness at typical kilovoltages (kVps).

b. The following aspects of the technologist's quality control tests were not evaluated:
- Processor quality control
- Phantom image quality control
- Repeat analysis
- Analysis of fixer retention
- Darkroom fog
- Screen-film contact
- Compression

c. Conducting an uniformity tests of mammography film screen cassettes

2. Personnel – Interpreting Physicians - 21 CFR 900.12(a)(1)(ii)(B)

There were inadequate records that the interpreting physician, [redacted] meets the minimum continuing education requirement of 15 hours of CME credits in a 36-month period.

Level 3 *Repeat* Finding:

Retention of Personnel Records - 21 CFR 900.12 (a)(4)

During the inspection at your facility and upon request by the inspector, your staff was unable to provide several required personnel qualification documentation for review by the inspector.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received. The problem is identified as **repeat Level 3** because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the problem found during your previous inspection on October 12, 1999.

Level 3 Finding:

Quality Assurance - General -21 CFR 900.12 (d)(1) & (2)

The Quality Assurance Program documentation lacked the required designation of a lead interpreting physician, quality control technologist(s); medical audit reviewing interpreting physician(s) and any other facility personnel with delegated quality assurance responsibilities.

It is necessary for you to act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please send a copy to the State radiation control office:

Mr. Dwight Leeseberg
Ohio Department of Health
161 South High St., Suite 400
Akron, OH 44308-1616

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/DWLeeseberg

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